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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/847,121	05/02/01	ROSENBLOOM R	QUIG-1002US

HM12/0718
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EXAMINER	
BAHAR, M	
ART UNIT	PAPER NUMBER
1617	2

DATE MAILED: 07/18/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No.	Applicant(s)	
	09/847,121	ROSENBLOOM, RICHARD	
	Examiner	Art Unit	
	Mojdeh Bahar	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-25 is/are pending in the application.

4a) Of the above claim(s) 7-9, 11, 14 and 16-25 is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-6, 10, 12-13 and 15 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-15, drawn to a composition for the treatment of diabetic neuropathy, classified in class 514, subclasses 458, 474, 456, 415, 456, 461, for example.

II. Claims 16-25, drawn to a method of treating diabetic neuropathy, classified in class 514, subclasses 458, 474, 456, 415, 456, 461, for example.

Inventions I and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case diabetic neuropathy can be treated with a formulation including a prostaglandin I derivative and an anti-diabetic agent.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

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Specie Election

Claims 1-25 are generic to a plurality of disclosed patentably distinct species comprising different aldose reductase inhibitor compounds and structurally diverse antioxidants.

These claims encompass species of aldose reductase inhibitor and antioxidant compounds that are so diverse and unrelated structurally that a reference anticipating one of the species would not anticipate or render obvious the other species. Thus the stated species are capable of supporting separate patents. To illustrate this diversity, consider the following examples of aldose reductase inhibitors: indole is classified in class 514, subclass 415, trifolin is classified in class 514, subclass 461; juglanin, apiin, rutin are classified in class 514, subclass 456, for example. To illustrate this diversity, consider the following examples of antioxidants: Vitamin E is classified in class 514, subclass 458; ascorbic acid is classified in class 514, subclass 474; lipoic acid is classified in class 514, subclass 440; rutin and fisetin are classified in class 514, subclass 456; for example.

During a telephone conversation with Kevin Dunleavy on July 10, 2001 a provisional election was made with traverse to prosecute the invention of Group I, claims 1-15 and species of aldose reductase inhibitor, quercetin and antioxidant, ascorbyl palmitate. Affirmation of this election must be made by applicant in replying to this Office action.

Claims 16-25 withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Claims 7-9, 11 and 14 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected specie, there being no allowable generic or linking claim.

Claims 1- 6, 10, 12-13 and 15 are herein examined on the merits in so far as they read on the elected species.

Claim Objections

Claim 6 is objected to because of the following informalities: The use of parenthetical expression "(Vitamin C)" in the claim is considered informal. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1,2, 6 and 7 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for Vitamin D3, does not reasonably provide enablement for "other Vitamin D3 derivatives which promote the synthesis of nerve growth factor". The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. One of ordinary skill in the art would not know how to determine the suitable vitamin D3 derivatives for the practice of this invention. The specification provides no guidance as to what parameters are used to define a suitable Vitamin D3 derivative for the practice of this invention. However as to what constitutes a "derivative", the specification on page 4 defines derivatives as "compounds which posses at least one structural moiety in common with the compound from which they are derived". This definition can give rise to many possible variations since the additional moieties can have varying structures. Furthermore the activity of the compounds based on their structural diversity is unpredictable and the specification provides no working examples. The Skilled Artisan would need to perform undue experimentation to determine which Vitamin D3 derivatives would be useful in practicing the present invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 1-15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The first line of claim 1 recites a "composition", see line 1, whereas line 3 of claim 1 refers to the "compositions" in the plural. It is therefore not clear whether the applicant intends to claim one composition or more than one composition. Further the expression "the compositions" in line 3 of claim1 lacks positive antecedent basis.

A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claim 2 recites the broad recitation "other vitamin D3 derivatives which promote the synthesis of nerve growth factor", and the claim also recites "Vitamin D3" which is the narrower statement of the range/limitation.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-6, 10, 12-13 and 15 are rejected under 35 U.S.C. 102(b) as being anticipated by Riley (US 5,976,568).

Riley (US 5,976,568) discloses an oral daily supplement comprising Vitamins D3 and C (Buffered Calcium Ascorbate, Ascorbic Acid and Ascorbyl Palmitate) and quercetin, see particularly claim 1 and Table II columns 25 and 36.

Note that recitation of intended use does not further limit a claim drawn to a composition.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mojdeh Bahar whose telephone number is (703) 305-1007. The examiner can normally be reached on (703) 305-1007 on Monday, Tuesday, Thursday and Friday from 8:30 a.m. to 6:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Minna Moezie, J.D., can be reached on (703) 308-4612. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Mojdeh Bahar
Patent Examiner
July 10, 2001

MINNA MOEZIE, J.D.
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600